

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference P51355		<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/20751	International filing date (day/month/year) 02 July 2003 (02.07.2003)	Priority date (day/month/year) 02 July 2002 (02.07.2002)	
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 39/44, 39/395 and US Cl.: 424/181.1			
Applicant SMITHKLINE BEECHAM CORPORATION			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 3 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of ___ sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand 29 January 2004 (29.01.2004)		Date of completion of this report 30 August 2004 (30.08.2004)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer Marianne DiBrino, Ph.D. Telephone No. 571-272-1690	

Form PCT/IPEA/409 (cover sheet)(July 1998)

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/20751

## I. Basis of the report

### 1. With regard to the elements of the international application:\*

- ☐ the international application as originally filed.
- ☒ the description:
  - pages 1-6 as originally filed
  - pages NONE, filed with the demand
  - pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the claims:
  - pages 7 as originally filed
  - pages NONE, as amended (together with any statement) under Article 19
  - pages NONE, filed with the demand
  - pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the drawings:
  - pages NONE, as originally filed
  - pages NONE, filed with the demand
  - pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the sequence listing part of the description:
  - pages 1/3-3/3 as originally filed
  - pages NONE, filed with the demand
  - pages NONE, filed with the letter of \_\_\_\_\_.

### 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

### 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in printed form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

### 4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

### 5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).  
 \*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/US03/20751**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>1-6</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-6</u>	NO
Industrial Applicability (IA)	Claims <u>1-6</u>	YES
	Claims <u>NONE</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1-6 lack an inventive step under PCT Article 33(3) as being obvious over R&D Focus Drug News (04 Oct. 1999) in view of US Patent No. 6,171,586 B1.

R&D Focus Drug News teaches the humanized mAb C242-DM1 alone and conjugated to a toxin, and administration of the conjugate to mice and humans.

R&D Focus Drug News does not teach the antibody formulated as recited in the instant claims.

US Patent No. 6,171,586 B1 discloses humanized mAbs at concentrations ranging from about 0.1 mg/ml to about 50 mg/ml in stable aqueous formulation comprising a polyol such as sucrose or trehalose in the concentration range from about 1% to about 15% w/v, succinic acid buffer at pH range from about 4.5 to about 6.0, and administration of the said antibody formulations to humans (especially Abstract, column 2 at lines 25-29, column 6 at lines 38-67, column 7 at lines 1-3, column 2 at lines 1-43, examples 1 and 2 and claims). US Patent No. 6,171,586 B1 further discloses that the said antibody formulations are stable following freezing and thawing of the formulation and are stable at a temperature of about 2-8 degrees C for at least one year (especially column 2 at lines 25-34).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have formulated the antibody or antibody conjugated taught by R&D Focus Drug News in the formulation disclosed by US Patent No. 6,171,586 B1.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to create stable aqueous formulations of the antibody taught by R&D Focus Drug News that are stable following freezing and thawing as taught by US Patent No. 6,171,586 B1 and for long term storage at about 2-8 degrees C for 1 year.

Claims 1-6 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.

**NEW CITATIONS**

US 6,171,586 B1 (LAM et al) 09 January 2001 (09.01.2001), see entire document.